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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,205	10/29/2001	Richard Anthony Godwin Smith	37945-0024	2596

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EXAMINER

SNEDDEN, SHERIDAN

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/936,205

**Applicant(s)**

SMITH ET AL.

**Examiner**

Sheridan K Snedden

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 14-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. This Office Action is in response to Paper filed 9 June 2004. Claims 2-6, 8, 11-13 are canceled. Applicant's amendment of claim 9 is acknowledged. Applicant's addition of new claims 14-18 is acknowledged. Claims 9, 14-18 are under examination.

### ***Withdrawal of Objections and Rejections***

2. All previous objections and/or rejections have been withdrawn.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 9 and 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Rittershaus *et al.* (US 6193979 B1). Rittershaus *et al.* teach that compositions that comprise a complement-related protein (CR1) in combination with the Lewis X antigen or the sialyl Lewis X antigen, a carbohydrate moiety. Rittershaus *et al.* teaches a soluble CR1 peptide, sCR1, and their use where organs prepared for transplant are perfused with the peptides. Alternatively, organs for transplantation are stored in solutions containing the peptides (see column 36, line 15). Rittershaus *et al.* teach formulations of the

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peptides with excipients including, for example, pharmaceutical grades of mannitol (column 37; regarding claim 14). The soluble CR1 peptides of Rittershaus *et al.* would inherently comprises SCRs, the sequence of 2 to 197 of SEQ ID NO: 1, and membrane binding elements consistent with claims 15-17. Thus, the reference clearly anticipates the invention as recited in the claims.

5. Claims 9 and 14, 15, 17 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith *et al.* (US 6713606 B1). Smith *et al.* teach CR1, which would comprise SCRs (claim 15) and membrane binding elements consistent with claim 17. Furthermore, Smith *et al.* teach soluble CR1 polypeptide is derivatized with an a myristoyl group (column 17, line 55; regarding claim 18). At column 18, Smith *et al.* teach the use of the peptides for Post-Ischemic Reperfusion Conditions. Thus, the reference clearly anticipates the invention as recited in the claims.

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rittershaus *et al.* (US 6193979 B1) in view of Smith *et al.* (US 6713606 B1). Rittershaus *et al.* teach compositions that comprise a complement-related protein (CR1) in combination with the Lewis X antigen or the sialyl Lewis X antigen, a carbohydrate

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moiety. Rittershaus *et al.* teaches a soluble CR1 peptide, sCR1, and their use where organs prepared for transplant are perfused with the peptides. Alternatively, organs for transplantation are stored in solutions containing the peptides (see column 36, line 15). Rittershaus *et al.* teach formulations of the peptides with excipients including, for example, pharmaceutical grades of mannitol (column 37; regarding claim 14). The soluble CR1 peptides of Rittershaus *et al.* would inherently comprises SCRs, the sequence of 2 to 197 of SEQ ID NO: 1, and membrane binding elements consistent with claims 15-17.

Rittershaus *et al.* does not teach complement-related protein (CR1) in combination with a with an a myristoyl group.

Smith *et al.* teach soluble CR1 polypeptide derivatized with an a myristoyl group (column 17, line 55; regarding claim 18).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the myristoylated CR1 polypeptide of Smith *et al.* for the CR1-lewis antigen composition in the method of perfusing an organ for the prevention of ischemic reperfusion injury as taught by Rittershaus *et al.* A person of ordinary skill in the art would have been motivated to make the above substitution because both composition are taught as having uses in the prevention of post-ischemic reperfusion injuries. Thus, a person of ordinary skill in the art would have expected success in perfusing an organ with the myristoylated CR1 polypeptide of Smith *et al.* Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious.

***Conclusion***

8. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

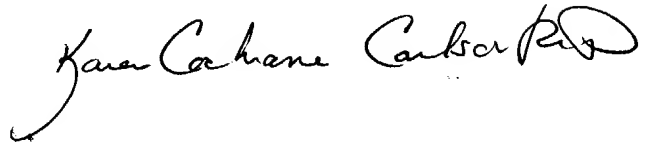
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in cursive script, reading "Karen Cochrane Carlson". The signature is written in dark ink and is positioned to the left of the printed name.

SKS  
August 23, 2004

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER

SKS